US006387130B1

(12) **United States Patent**
Stone et al.

(10) **Patent No.: US 6,387,130 B1**
(45) **Date of Patent: May 14, 2002**

(54) **SEGMENTED LINKED INTERVERTEBRAL IMPLANT SYSTEMS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/549,779**

(22) Filed: **Apr. 14, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/129,703, filed on Apr. 16, 1999.

(51) **Int. Cl.**[7] **A61F 2/44**
(52) **U.S. Cl.** **623/17.16**
(58) **Field of Search** 623/17.11, 17.16, 623/16.11

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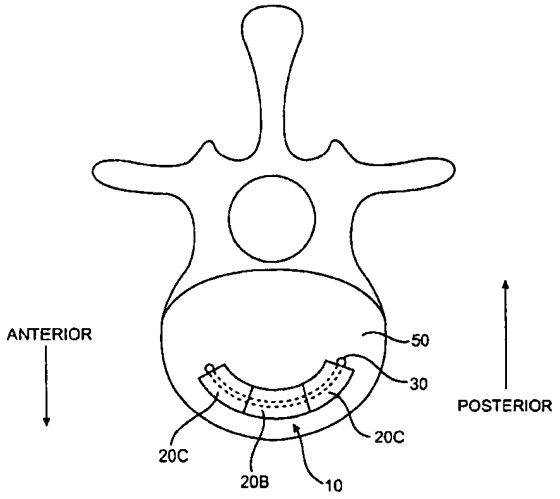
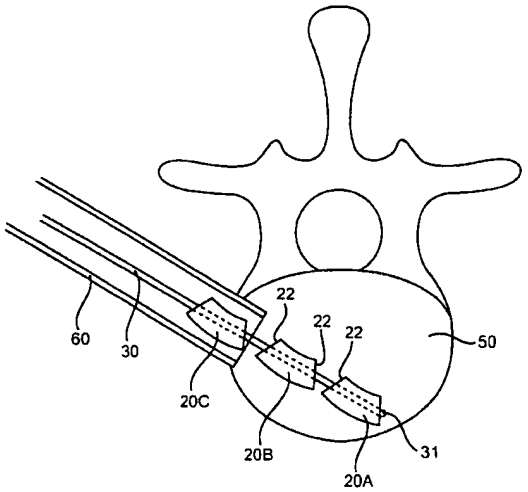
(57) **ABSTRACT**

A method of positioning a plurality of intervertebral implants in a patient's intervertebral space, comprising: introducing an elongated member into the patient's intervertebral space; and sequentially advancing a plurality of intervertebral implants over the elongated member and into the patient's intervertebral space, the plurality of intervertebral implants each having at least one hole passing therethrough, with the elongated member received through the holes passing through each of the plurality of implants.

34 Claims, 10 Drawing Sheets





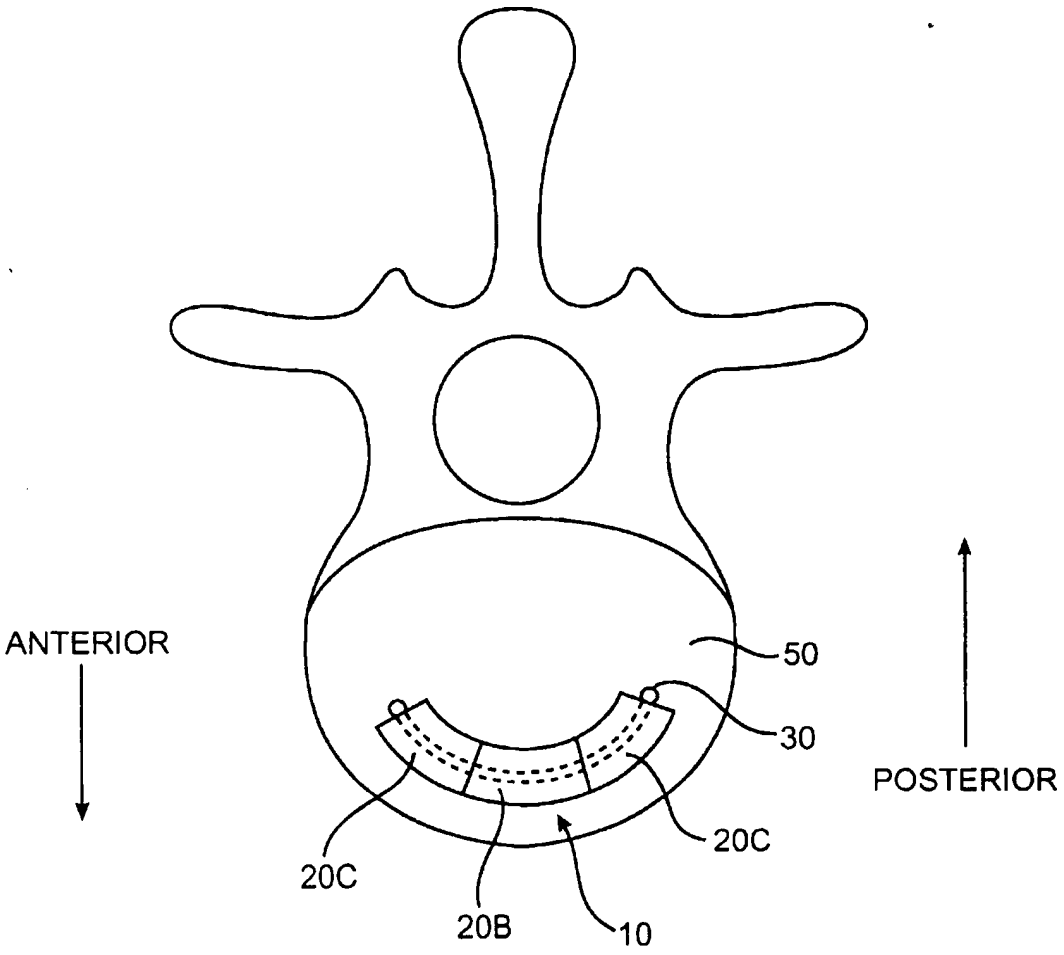


FIG. 1

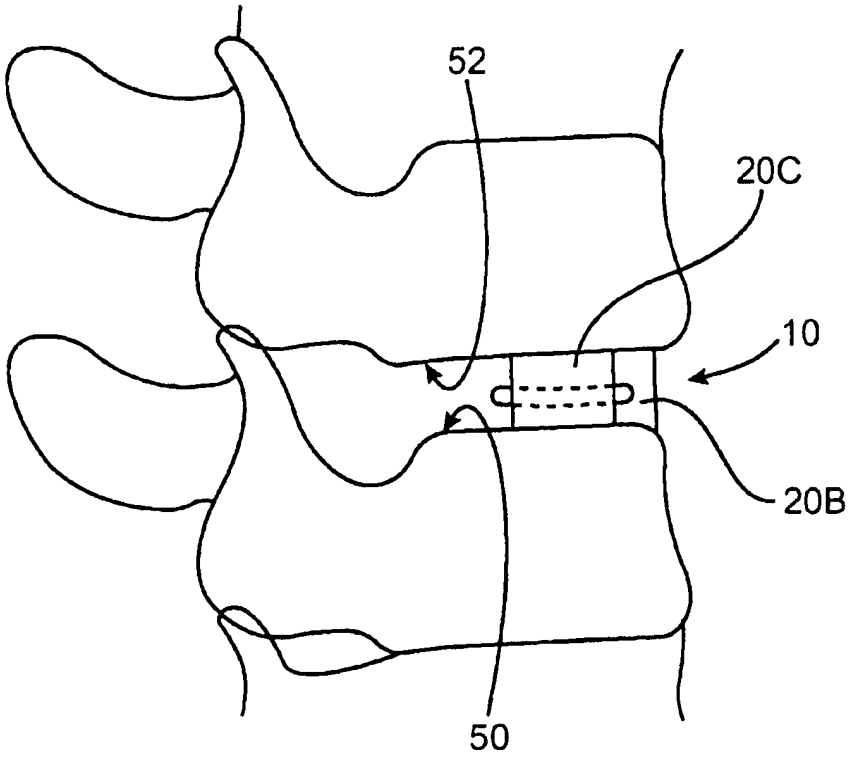


FIG. 2

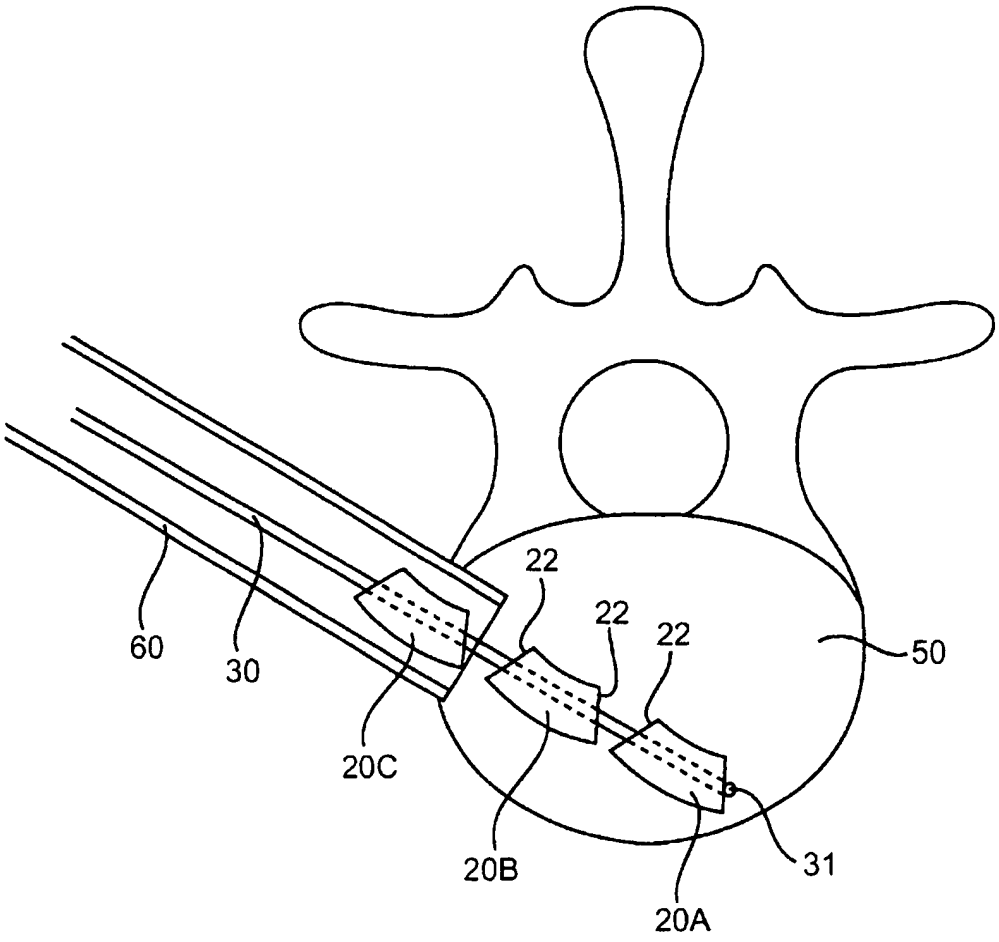


FIG. 3

FIG. 4A

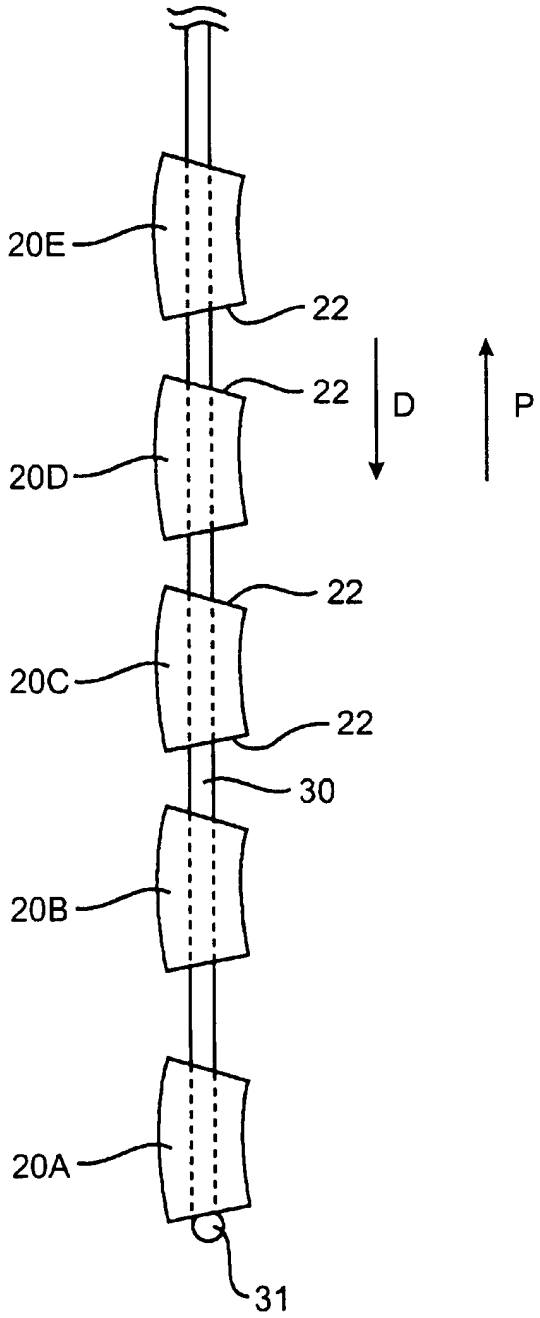
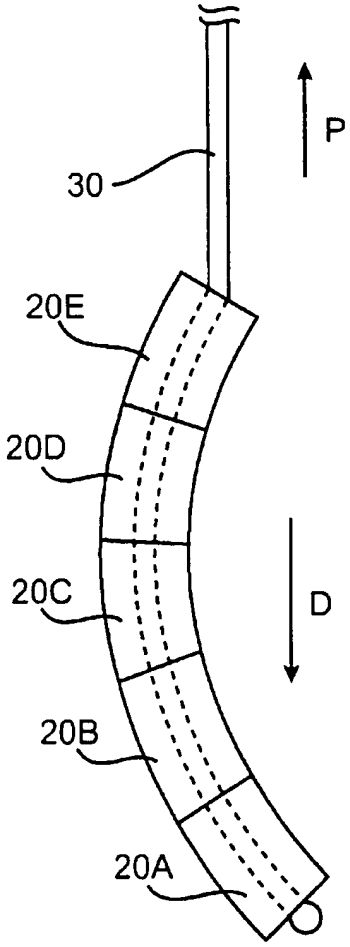


FIG. 4B



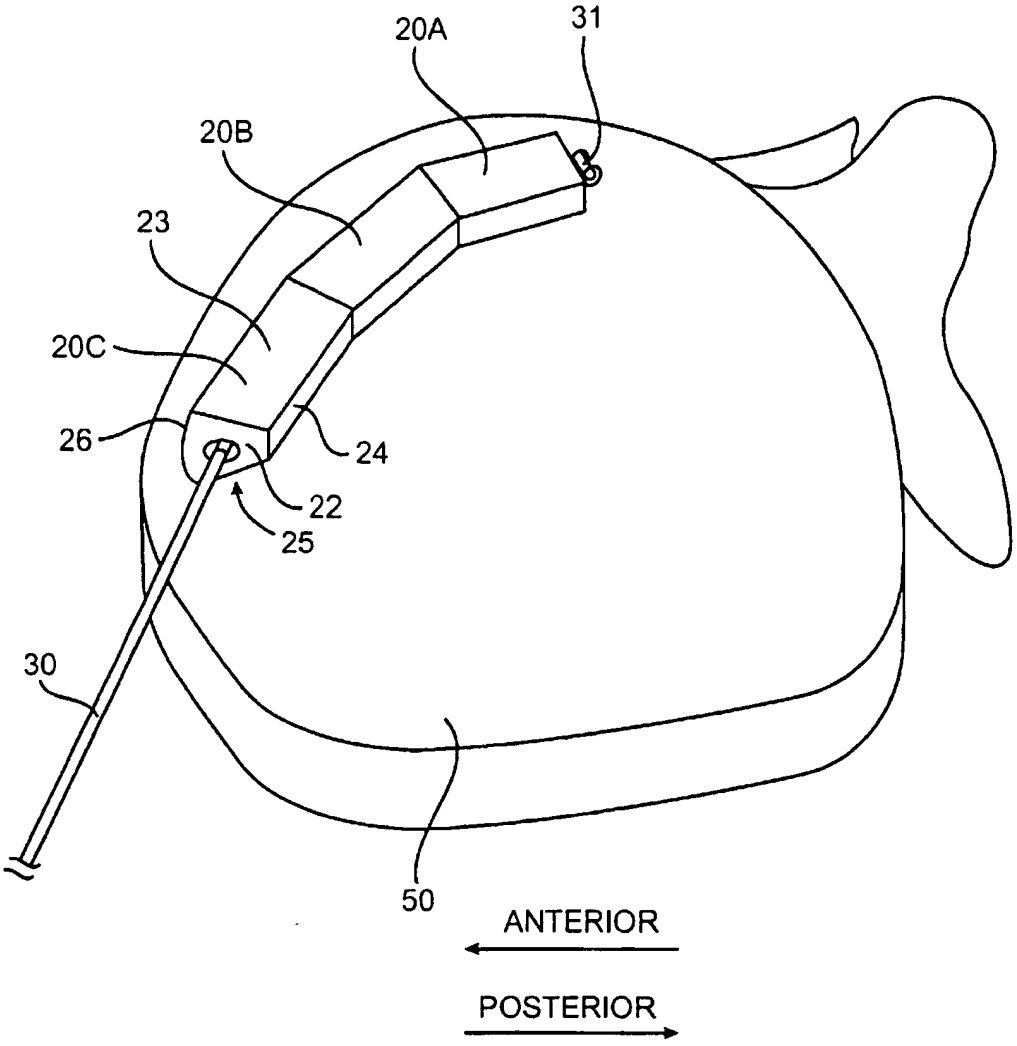
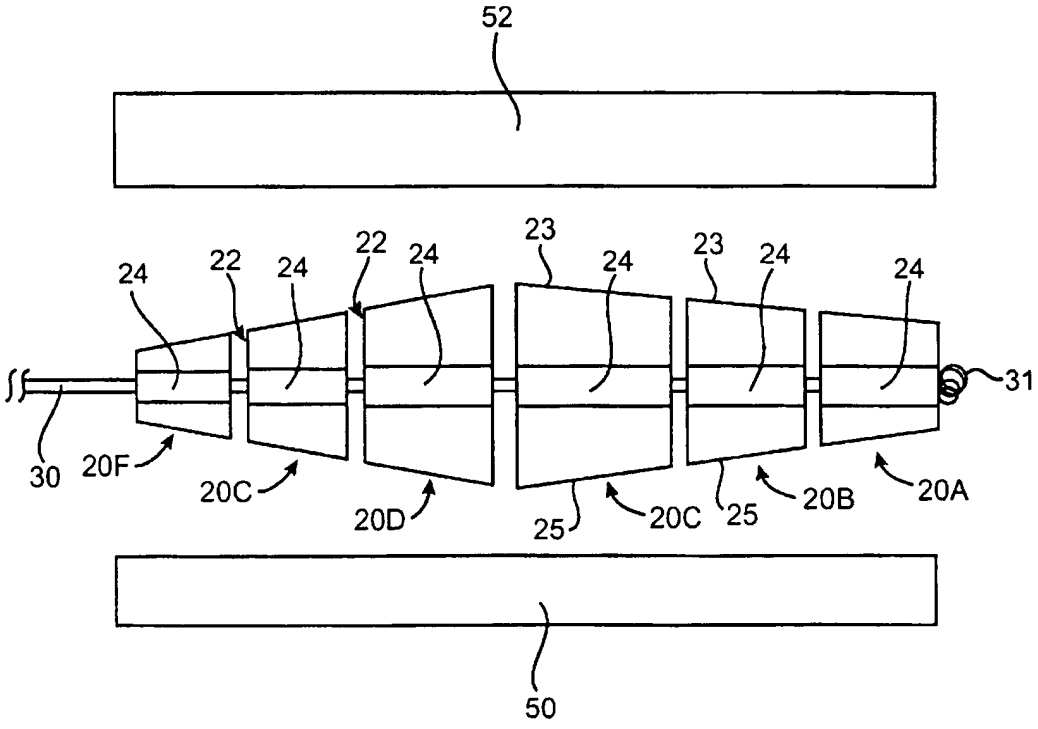


FIG. 5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20A
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FIG. 6

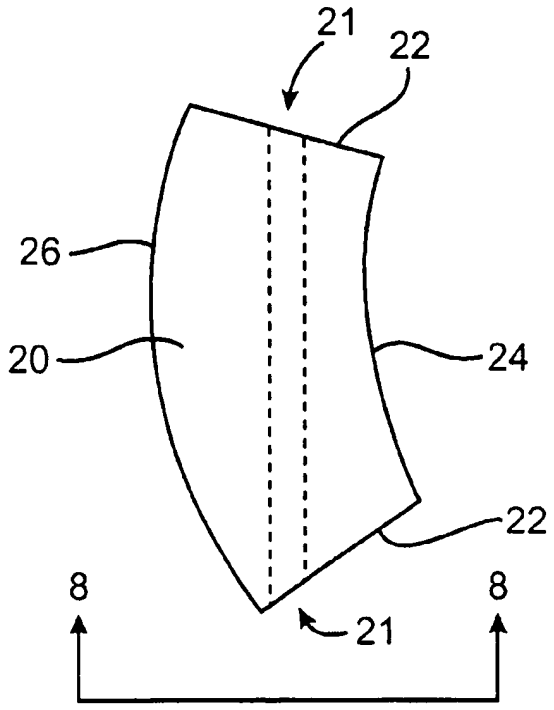

FIG. 7

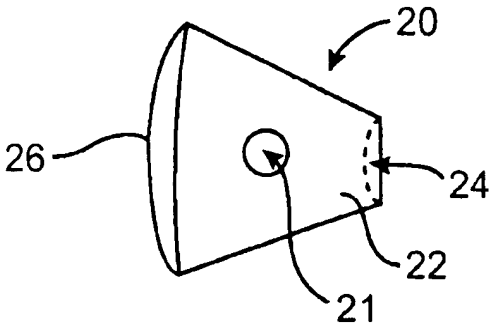

FIG. 8

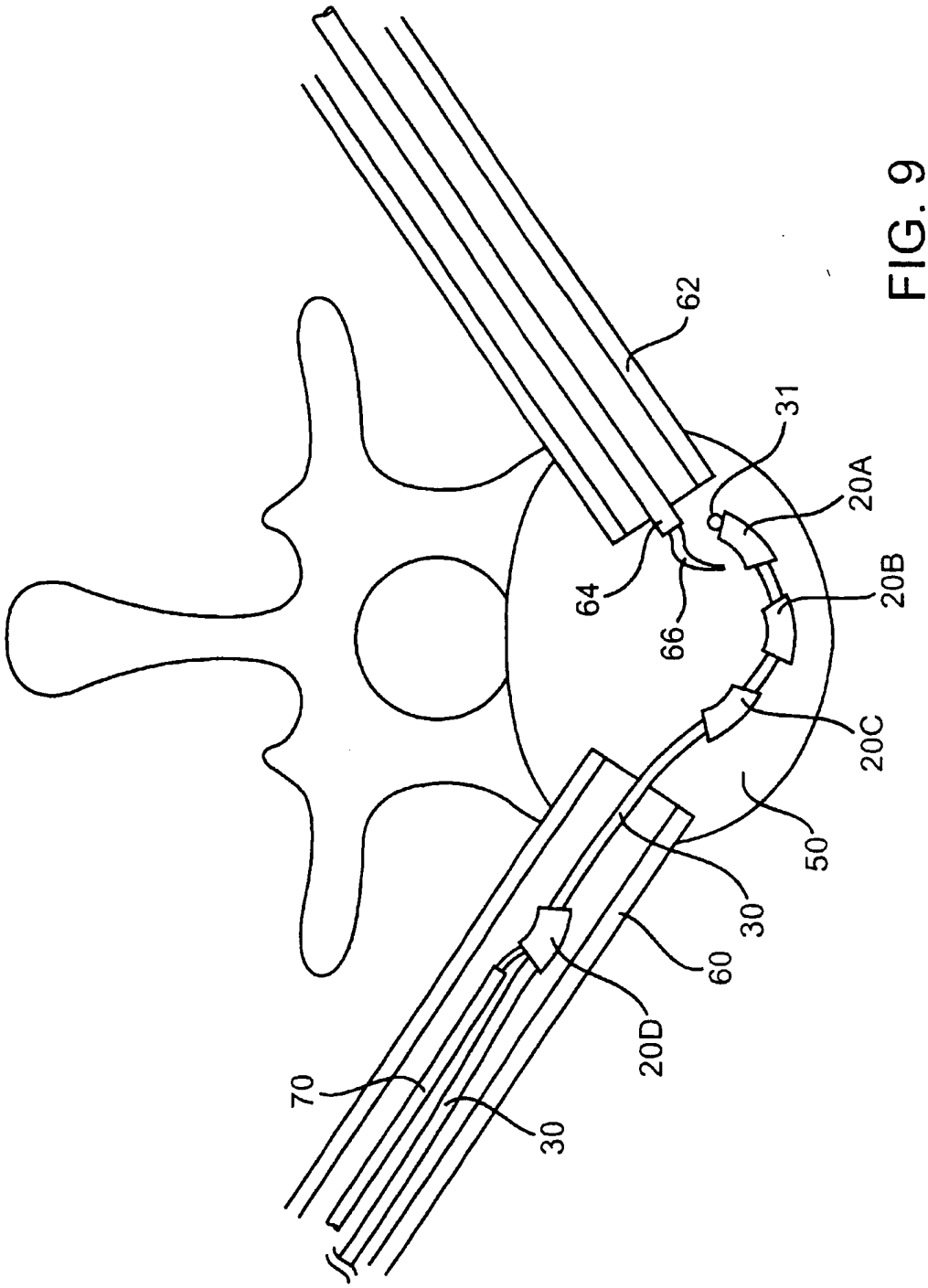

FIG. 9

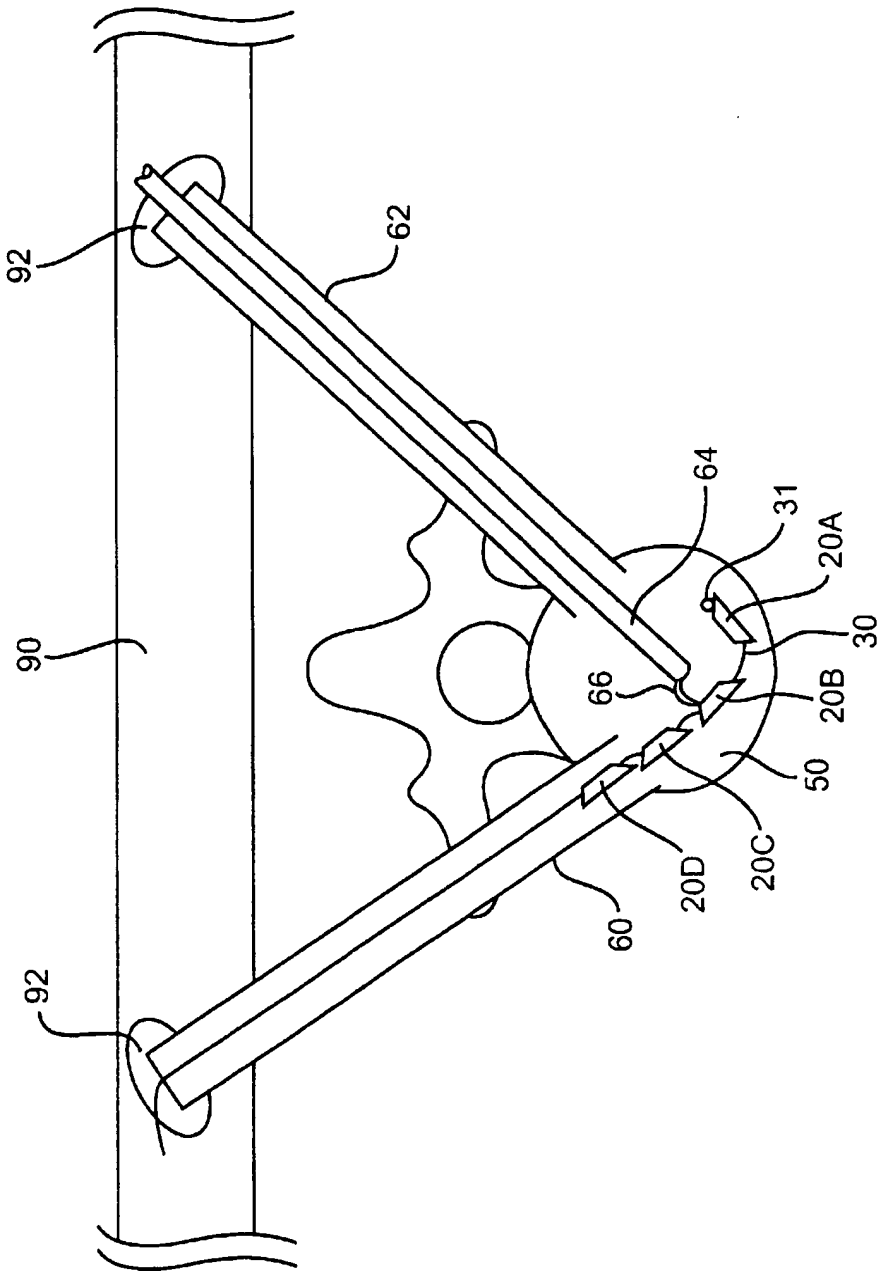

FIG. 10

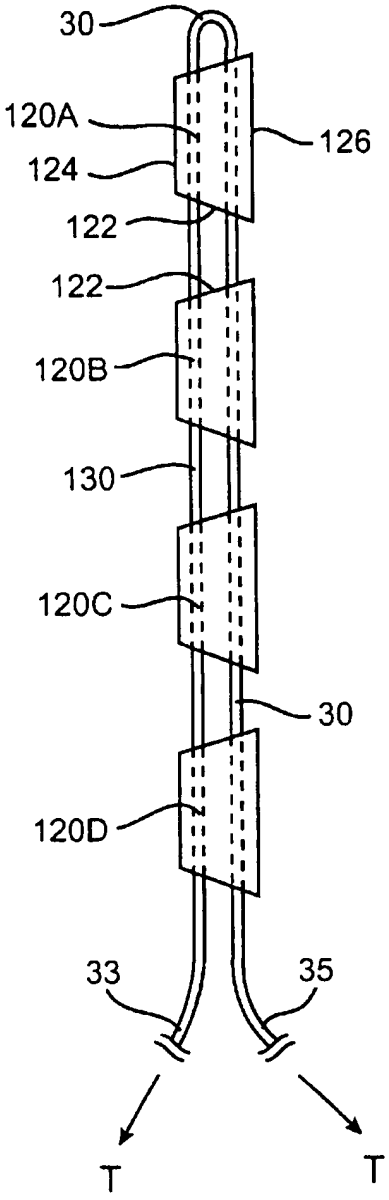

FIG. 11A

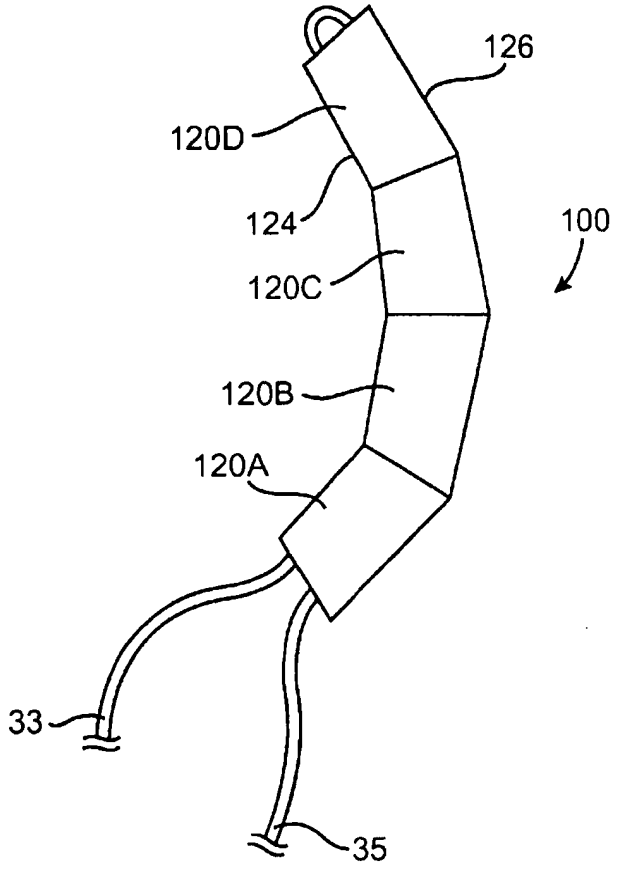

FIG. 11B

SEGMENTED LINKED INTERVERTEBRAL IMPLANT SYSTEMS

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a regular patent application of and claims the benefit of priority from U.S. Provisional patent application Ser. No. 60/129,703 filed Apr. 16, 1999, the full disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

The present invention is related to spinal fixation and stabilization systems in general and to intervertebral implant systems for promoting arthrodesis in particular.

BACKGROUND OF THE INVENTION

Stabilization of vertebrae relative to each other, primarily for the purposes of indirect nerve decompression and fusion (arthrodesis), is an well-accepted surgical objective. To date, most methods entail a two staged process of intervertebral distraction and then subsequent interposition of either a cortical bone graft or an inorganic implant to maintain the relative position of the vertebrae during the healing phase of arthrodesis.

Many variations of this basic surgical technique exist. Unfortunately, these systems often require considerable time and effort for successful implant placement. This is frequently due to the fact that such systems typically require both excessive surgical tissue dissection and mechanical vertebral distraction such that the various stabilization component(s) of the system can be successfully positioned in a patient's intervertebral space.

In addition, the dimensional constraints typically imposed by access considerations are often in conflict with the desire to place the largest implant possible to support the loads transmitted across the vertebral endplates. Specifically, the larger the implant inserted, the greater the amount of resulting tissue damage both in the intervertebral space, and in the surrounding tissues.

An additional problem with many intervertebral implant devices is that they do not confer a proper lordotic relationship between the vertebrae, either as a consequence of their geometry or their insertion method.

SUMMARY OF THE INVENTION

The present invention provides an intervertebral implant system, comprising; a plurality of implants, each implant having at least one hole passing therethrough; and an elongated member dimensioned to pass through the holes in each of the plurality of implants. In a preferred method, the plurality of intervertebral implants are positioned in a patient's intervertebral space by; introducing the elongated member into the patient's intervertebral space; and sequentially advancing a plurality of intervertebral implants over the elongated member and into the patient's intervertebral space.

In preferred aspects of the invention, the elongated member comprises a cord, string, tether or suture which is used to hold together the plurality of intervertebral implants such that together they form an implant assembly which is positioned between two adjacent vertebrae.

In preferred aspects, each of the intervertebral implants have ends which are angled such that when the implants are pulled or pushed together, they will tend to form a generally C-shaped assembly, which may easily be positioned between two vertebral endplates around the curved perimeter of the patient's intervertebral space.

As will be explained, another advantage of the present system is that the degree of curvature exhibited by the C-shaped implant assembly can itself be selected by selecting implants which are dimensioned with their ends being disposed at preferred angles.

Another important advantage of the present system is that it can be deployed through a narrow operating cannula. As such, the present system advantageously permits the placement of a load supporting implant assembly over a large area between two of the patient's vertebrae, but without requiring that a large diameter access portal pass through the patient and into the patient's intervertebral space.

Therefore, the present system is ideally suited to be introduced into a patient in a minimally invasive surgical procedure, with minimal disturbance to the soft musculature and ligament tissue structures in the spinal region. In contrast, the placement of existing intervertebral implant systems typically compromises such tissues.

Another important advantage of the present system is that it provides an assembly (comprising a plurality of intervertebral implants) which can easily be positioned around the curved perimeter of the patient's intervertebral surface, such that the assembly is positioned on the denser portion of the vertebral endplates (i.e.: the perimeter) to provide enhanced support between the two adjacent vertebrae.

In an optional preferred aspect, at least some of the plurality of individual intervertebral implants have top and bottom surfaces which are angled to one another such that the plurality of intervertebral implants form an assembly which tapers in a lordotic angle when the implants are abutted together end-to-end. Therefore, another advantage of the present system is that the overall implant assembly can preferably be shaped to provide a proper lordotic angle between the adjacent vertebrae when positioned therebetween.

In various optional aspects of the invention, a positioning rod can be used to position each of the separate implants. In one aspect, the separate implants are pushed tightly together, such that they form a C-shaped assembly.

In additional aspects, the elongated member passing through each of the implants can be withdrawn or tightened such that the individual implants are tightened together to abut tightly against one another end-to-end.

As will be explained, an operating cannula(e) and a surgical guideframe for positioning the operating cannula(e) may also preferably by used.

Other advantages of the present system include reduction both in the amount of vertebral distraction and tissue dissection required, thereby decreasing surgical time, complexity and trauma to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top (sagittal) plan view of a support assembly comprising a plurality of intervertebral implants positioned together around the anterior perimeter of a patient's vertebral endplate in accordance with the present invention.

FIG. 2 is a side (lateral) view corresponding to FIG. 1.

FIG. 3 is a top (sagittal) plan view of the intervertebral implants of FIG. 1 being sequentially advanced over an elongated member.

FIG. 4A shows a plurality of intervertebral implants spaced apart on an elongated member.

FIG. 4B shows a plurality of intervertebral implants pushed together on an elongated member.

FIG. 5 is a perspective view showing 3 implants positioned on top of a vertebral endplate.

FIG. 6 is a schematic illustration of a plurality of intervertebral implants positioned between two vertebral endplates in an anterior-posterior view.

FIG. 7 is a top plan view of a single intervertebral implant.

FIG. 8 is a side elevation view taken along line 8—8 in FIG. 7.

FIG. 9 is an illustration of a preferred method of placement of the intervertebral implants.

FIG. 10 is an illustration of a preferred method of placement of the intervertebral implants using a surgical guideframe with operating cannulae supported by the surgical guideframe.

FIG. 11A shows a plurality of intervertebral implants spaced apart on an elongated member, the elongated member being received twice through each implant.

FIG. 11B shows a plurality of intervertebral implants pushed together on an elongated member, the elongated member being received twice through each implant.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides systems, devices and methods for placing a plurality of intervertebral implants within a patient's intervertebral space, such that the individual implants form an implant assembly which is ideally suited to promote spinal fusion (arthrodesis) and to provide load bearing stabilization between adjacent vertebrae.

Referring to FIG. 1, the present invention provides a generally C-shaped assembly **10** which is preferably positioned to provide support between adjacent vertebral endplates **50** and **52** (FIG. 2). Implant assembly **10** is formed from a plurality of separate individual intervertebral inserts **20A**, **20B**, and **20C** which have been pushed together end-to-end, abutting one another as shown.

It is to be understood that different number of individual implants can be assembled to form implant assembly **10**, depending upon the particular dimensions both of the individual implants and the patient's intervertebral space. Accordingly various implant assemblies having **3** (FIG. 1), **5** (FIG. 4A) and **6** (FIG. 6) are shown, and the present invention is not limited to any particular number of individual implants.

Returning to FIG. 1, each of individual intervertebral implants **20A**, **20B**, and **20C** are preferably formed with at least one hole (**21** in FIG. 7) running therethrough. An elongated member **30** is threaded through holes **21** on each of intervertebral implants **20A**, **20B**, and **20C** such that implants **20A**, **20B**, and **20C** can be sequentially advanced thereover, as will be explained.

Referring to FIG. 3, elongated member **30**, (which may preferably comprise a wire, string, cord, tether or suture), is first advanced (for example, through cannula **60**) into a patient's intervertebral space. Thereafter, implants **20A**, **20B**, and **20C** are then sequentially introduced thereover. Elongated member **30** preferably has an enlarged end (in the case of the member being a wire) or a knot **31** (in the case of the elongated member being a suture) at its distal end. Therefore, implant **20A** will come to rest at the distal end of member **30** when advanced thereover, as shown.

Thereafter, the plurality of intervertebral inserts will be pushed tightly together such that their angled ends **22** will abut against one another, causing assembly **10** to assume a curved C-shape as seen in FIG. **1**. FIG. **4A** shows the formation of a curved implant assembly **10** in more detail. Specifically, as shown in FIG. **4A**, a plurality of intervertebral implants **20A**, **20B**, **20C**, **20D** and **20E** are advanced distally in direction D over elongated member **30** until implant **20A** abuts against knot **31**. Thereafter, as shown in FIG. **4B**, by either or both of :(1) pushing implant **20E** in distal direction D, or (2) pulling elongated member **30** in proximal direction P, angled ends **22** of each of implants **20** will abut together causing assembly **10** to assume a curved C-shape.

An advantage of assembly **10** assuming a curved C-shape is that it can easily be positioned at a location around the anterior perimeter of vertebral endplate **50**, as shown in FIGS. **1** and **5**. Moreover, the present invention can be assembled within the patient's intervertebral space to provide support to a large area between vertebral endplates **50** and **52**, without the diameter of cannula **60** limiting the size of the assembly.

In various aspects of the invention, elongated member **30** comprises a monofilament or braided suture. Alternatively, elongated member **30** may comprise a flexible wire, which may optionally be made of a shape memory metal such as Nitinol™ As such, wire **30** may be pre-formed to assume a desired curved shape when introduced into the patient's intervertebral space such that the plurality of implants can easily be sequentially introduced thereover.

Referring to FIG. **5**, each of the plurality of intervertebral implants can be dimensioned such that when pulled or pushed together to form an implant assembly, the implant assembly will maintain a proper lordotic angle between the adjacent vertebrae, as follows. Implant **20C** (which is adapted to be positioned approximately at the lateral mid line through the vertebral endplates) may have a short or narrow first (interior) side **24**, and a tall or wide (exterior) side **26**, such that top **23** and bottom **25** are angled such that implant **20C** assumes a tapered shape to maintain a proper lordotic angle between vertebral endplates **50** and **52** (not shown).

Referring to FIG. **6**, each of the plurality of intervertebral implants can be dimensioned such that when pulled or pushed together to form an implant assembly, the formation of the implant assembly will itself assist in vertebral distraction, as follows. Each of implants **20** may also have tops **23** and bottoms **25** which are angled to elongated member **30**, as shown. An first advantage of having slanting tops **23** and bottoms **25** is that as inserts **20A** to **20C** are sequentially advanced over elongated member **30** toward knot **31**, successive inserts **20A** to **20C** will each be slightly taller than the previously inserted implant such that successive inserts tend to pry apart (i.e.: distract) the adjacent vertebrae. A second advantage of having tops **23** and bottoms **25** slant both as shown in FIG. **6** and as in FIG. **5** is that together such slanting will give the implants a tapered shape which assists in providing a preferred lordotic angle between the adjacent vertebrae. It is to be understood that to achieve a proper lordotic angle, each of implants **20A**, **20B**, **20C**, etc. may be shaped slightly differently depending upon the final location (around the endplate perimeter) at which the respective implant is to be positioned. (FIG. **6** is shown in an exploded view with the angles of tops **23** and bottoms **25** exaggerated for clarity of illustration purposes).

FIGS. **7** and **8** show further details of the preferred geometry of a single intervertebral implant **20**.

FIG. **9** shows an optional preferred method of inserting implants **20A**, **20B** and **20C** in which elongated member **30**

is inserted into the patient's intervertebral space, and implants **20A**, **20B** and **20C** are sequentially inserted over elongated member **30**. A positioning rod **64** (having a hook **66** at its distal end) is advanced through a second operating cannula **62** and is used to manually adjust the positioning of each of implants **20A**, **20B** and **20C**. As can also be seen, a positioning tool **70** can be inserted through operating cannula **60**, to both advance implant **20D** distally forward (such that it together forms an implant support assembly **10** with implants **20A**, **20B** and **20C**), and to push against implant **20D** when elongated member **30** is withdrawn (i.e.: pulled taught) in cannula **60**.

FIG. **10** illustrated a preferred method of placement of the intervertebral implants using a surgical guideframe **90** with operating cannulae supported by cannula guides **92** of surgical guideframe **90**, and is ideally suited to be performed with the surgical guideframe set forth in Applicant's co-pending U.S. patent application Ser. No. 09/326,739, filed Jun. 4, 1999, and incorporated herein by reference in its entirety for all purposes.

FIGS. **11A** and **11B** show a plurality of implants **120A**, **120B**, **120C** and **120D**, each having two parallel holes passing therethrough such that elongated member **30** may be threaded back and forth therethrough, (as partially shown in dotted lines in FIG. **11A**). As elongated member **30** is pulled taught, (i.e.: with ends **33** and **35** being pulled taught in directions T), a curved shaped intervertebral assembly **100** will be formed.

As also show in FIGS. **11A** and **11B**, implants **120** may have straight sides **124** and **126**, (as opposed to curved sides **24** and **26** of implants **20**. As can be seen, ends **122** of implants **120** are preferably angled to a central longitudinal axis extending through the implant parallel to the holed through which elongated member **30** is received.

An advantage of the aspect of the invention shown in FIGS. **11A** and **11B** is that (having parallel holes passing through each of the implants **120**) stability will be enhanced. Moreover, elongated member **30** may be cut (after assembly **100** is formed) such that ends **33** and **35** can simply be tied, or otherwise fused, together.

In any of the above aspects of the invention where elongated member **30** passes through one or two hole(s) in each of the implants, the elongated member may be cut and tied (or fused into a knot) at the proximal end of the assembly such that it securely holds the plurality of implants together in an assembly. As such, a portion of elongated member **30** preferably remains within the patient's intervertebral space, tying (or otherwise securing) the separate implants together and-to-end forming the preferred intervertebral implant assembly.

What is claimed is:

1. An intervertebral implant system, comprising:

a plurality of implants, each implant having at least one hole passing therethrough; and

an elongated member dimensioned to pass through the holes in each of the plurality of implants, wherein the plurality of implants are slidingly movable over the elongated member, and wherein the plurality of implants can be positioned to abut against one another.

2. The intervertebral implant system of claim **1**, wherein, the elongated member is selected from the group consisting of a cord, string, tether or suture.

3. The intervertebral implant system of claim **1**, wherein, the elongated member comprises braided suture material.

4. The intervertebral implant system of claim **1**, wherein, the elongated member comprises a flexible wire.

5. The intervertebral implant system of claim **4**, wherein, the wire is made of a shape-memory metal.

6. The intervertebral implant system of claim **1**, wherein, the at least one hole comprises two holes passing through each of the intervertebral implants.

7. The intervertebral implant system of claim **6**, wherein, the two holes pass through each of the intervertebral implants in parallel to one another.

8. The intervertebral implant system of claim **7**, wherein, a single elongated member is threaded through both of the holes.

9. The intervertebral implant system of claim **1**, wherein, at least some of the plurality of intervertebral implants have ends which are angled to a central longitudinal axis extending through the implant.

10. The intervertebral implant system of claim **9**, wherein, the plurality of intervertebral implants form a curved assembly when the angled ends of the implants are abutted together end-to-end.

11. The intervertebral implant system of claim **1**, wherein, at least some of the plurality of intervertebral implants have top and bottom surfaces which are angled to one another such that the plurality of intervertebral implants form an assembly which tapers in a lordotic angle when the implants are abutted together end-to-end.

12. The intervertebral implant system of claim **1**, wherein, each implant has two curved sides, and wherein one of the curved sides is concave and the other curved side is convex.

13. The intervertebral implant system of claim **1**, further comprising:

a positioning rod for adjusting the position of each of the intervertebral implants.

14. The intervertebral implant system of claim **13**, further comprising:

first and second operating cannula, wherein the elongated member and the plurality of implants are dimensioned to be received through the first operating cannula, and the positioning rod is dimensioned to be received through the second operating cannula.

15. The intervertebral implant system of claim **14**, further comprising:

a surgical guideframe adapted to support the first and second operating cannula.

16. A method of positioning a plurality of intervertebral implants in a patient's intervertebral space, comprising:

introducing an elongated member into the patient's intervertebral space; and

sequentially advancing a plurality of intervertebral implants over the elongated member and into the patient's intervertebral space, the plurality of intervertebral implants each having at least one hole passing therethrough, with the elongated member received through the holes passing through each of the plurality of implants.

17. The method of claim **16**, wherein sequentially advancing the plurality of intervertebral implants comprises:

advancing the plurality of intervertebral implants over the elongated member such that they abut one against another.

18. The method of claim **16**, wherein the elongated member passes through two holes in each implant.

19. The method of claim **17**, wherein advancing the plurality of intervertebral implants over the elongated member such that they abut one against another, comprises:

distally pushing on the last of the sequence of intervertebral implants, thereby causing the implants to abut together, forming a curved implant assembly.

20. The method of claim 19, wherein distally pushing on the last of the sequence of intervertebral implants comprises pushing with a positioning rod.

21. The method of claim 17, wherein advancing the plurality of intervertebral implants over the elongated member such that they abut one against another, comprises:

drawing back on the elongated member, thereby causing the plurality of intervertebral implants to abut together, forming a curved implant assembly.

22. The method of claim 19 or 21, wherein, at least some of the plurality of intervertebral implants have ends which are angled to a central longitudinal axis extending through the implant.

23. The method of claim 21, wherein the curved implant assembly is positioned around a portion of the perimeter of the patient's intervertebral space.

24. The method of claim 16, further comprising:

positioning at least some of the plurality of intervertebral implants with a positioning rod.

25. The method of claim 16, further comprising:

cutting the elongated member such that a portion of the elongated member passing through the plurality of intervertebral implants remains disposed therein after the remainder of the elongated member has been removed from the intervertebral space.

26. The method of claim 25, further comprising:

forming a knot in an end of the portion of the elongated member passing through the plurality of intervertebral implants such that the plurality of intervertebral implants are held together.

27. The method of claim 25, further comprising:

connecting together separate ends of the portion of the elongated member passing through the plurality of intervertebral implants such that the plurality of intervertebral implants are held together.

28. The method of claim 16, wherein, the elongated member and the plurality of intervertebral implants are advanced through a first operating cannula into the intervertebral space, the first operating cannula being supported in a surgical guideframe.

29. The method of claim 28, wherein, a positioning rod is advanced through a second operating cannula into the intervertebral space, the second operating cannula being supported in a surgical guideframe.

30. An intervertebral implant system, comprising:

a plurality of implants, each implant having at least one hole passing therethrough; and

an elongated member dimensioned to pass through the holes in each of the plurality of implants, wherein, the at least one hole comprises two parallel holes passing through each of the intervertebral implants, and wherein the elongated member is threaded through both of the holes.

31. An intervertebral implant system, comprising:

a plurality of implants, each implant having at least one hole passing therethrough; and

an elongated member dimensioned to pass through the holes in each of the plurality of implants, and wherein at least some of the plurality of intervertebral implants have ends which are angled to a central longitudinal axis extending through the implant, and wherein the plurality of intervertebral implants form a curved assembly when the angled ends of the implants are abutted together end-to-end.

32. An intervertebral implant system, comprising:

a plurality of implants, each implant having at least one hole passing therethrough; and

an elongated member dimensioned to pass through the holes in each of the plurality of implants, wherein each implant has two curved sides, and wherein one of the curved sides is concave and the other curved side is convex.

33. An intervertebral implant system, comprising:

a plurality of implants, each implant having at least one hole passing therethrough; and

an elongated member dimensioned to pass through the holes in each of the plurality of implants;

a positioning rod for adjusting the position of each of the intervertebral implants; and

first and second operating cannula, wherein the elongated member and the plurality of implants are dimensioned to be received through the first operating cannula, and the positioning rod is dimensioned to be received through the second operating cannula.

34. An intervertebral implant system, comprising:

a plurality of implants, each implant having at least one hole passing therethrough; and

an elongated member dimensioned to pass through the holes in each of the plurality of implants;

a positioning rod for adjusting the position of each of the intervertebral implants;

first and second operating cannula, wherein the elongated member and the plurality of implants are dimensioned to be received through the first operating cannula, and the positioning rod is dimensioned to be received through the second operating cannula; and

a surgical guideframe adapted to support the first and second operating cannula.

* * * * *

US005755797A

United States Patent [19]

Baumgartner

[11] Patent Number: 5,755,797

[45] Date of Patent: May 26, 1998

[54] **INTERVERTEBRAL PROSTHESIS AND A PROCESS FOR IMPLANTING SUCH A PROSTHESIS**

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[73] Assignee: **Sulzer Medizinaltechnik AG**, Winterthur, Switzerland

[21] Appl. No.: **724,937**

[22] Filed: **Oct. 2, 1996**

Related U.S. Application Data

[63] Continuation of Ser. No. 223,489, Apr. 5, 1994.

[30] **Foreign Application Priority Data**

Apr. 21, 1993 [EP] European Pat. Off. 93810291

[51] **Int. Cl.**[6] **A61F 2/44**

[52] **U.S. Cl.** **623/17**

[58] **Field of Search** 623/17, 11; 606/61

[56] **References Cited**

U.S. PATENT DOCUMENTS

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Primary Examiner—Michael J. Milano

Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

An implant consisting of several support members (7), which are produced from an elastic plastic, is provided as a replacement for a part, which is no longer capable of bearing loads, of the core region of an intervertebral disk (3). The support members (7) are inserted one after the other into a central cavity (5) constructed in the core region by means of a tube (6) passing through an outer annular region (4) of the intervertebral disk (3) until said cavity is filled. When the cavity (5) becomes clogged with the filling members (7), they become deposited on the boundary walls of the annular region (4) and against one another and are elastically deformed under stress. Accordingly a universal implant which can be adapted to cavities (5) of any shape, and which forms a relatively compact, elastic support structure, can be achieved.

13 Claims, 3 Drawing Sheets

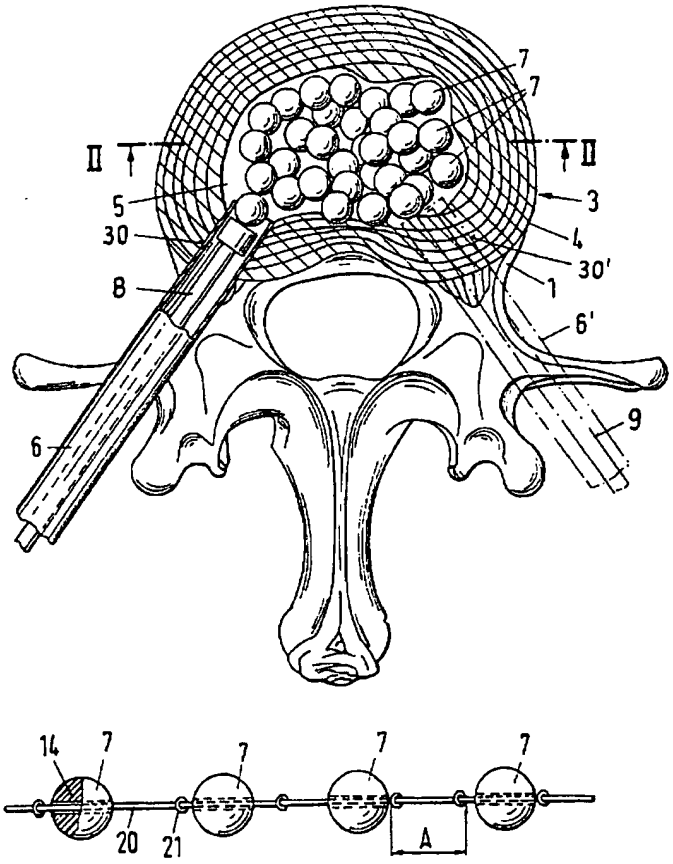


Fig.1

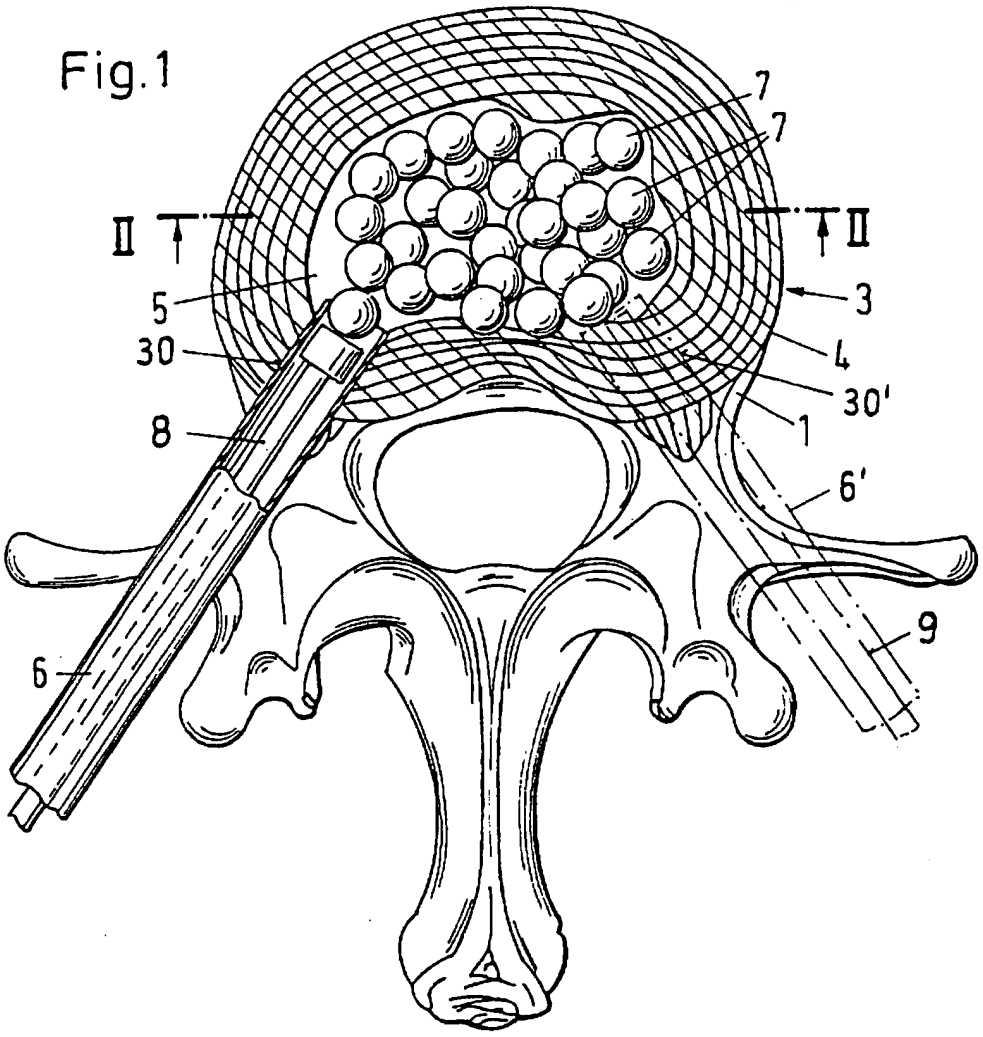


Fig.2

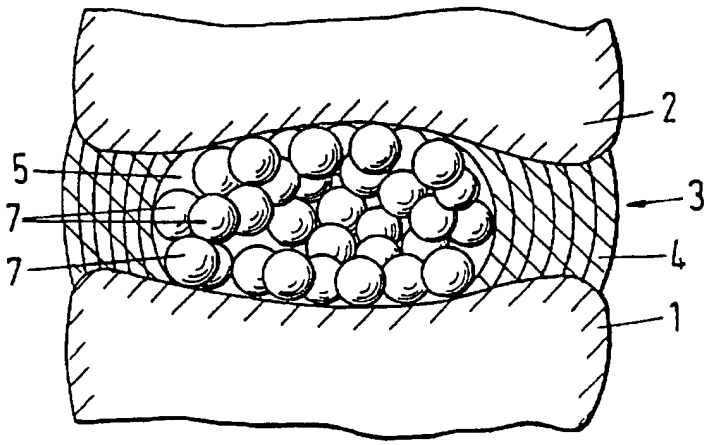


Fig. 3

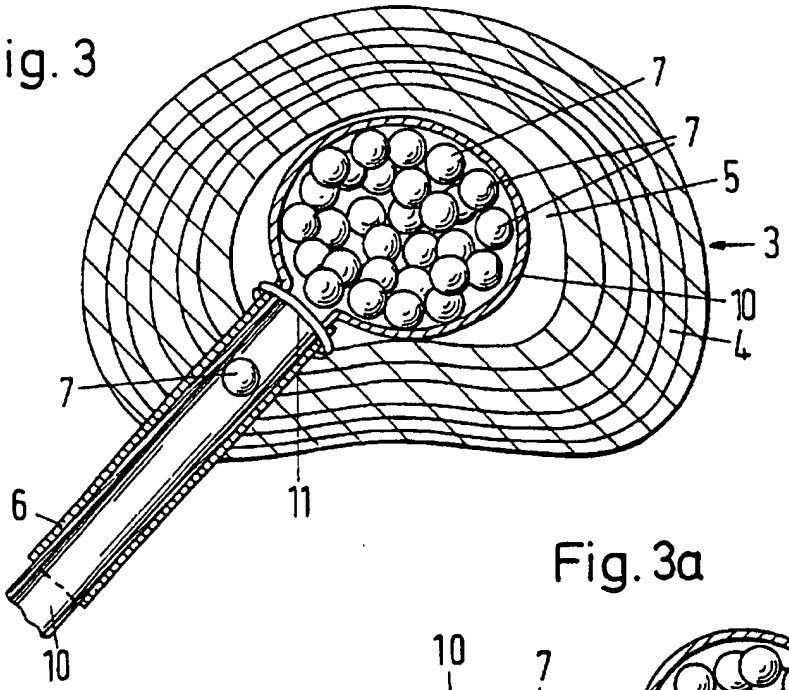


Fig. 3a

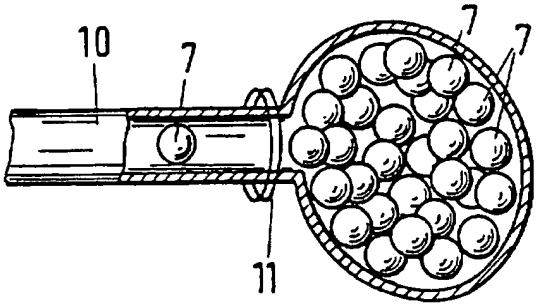


Fig. 4a

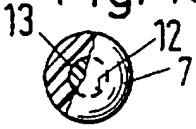


Fig. 4b

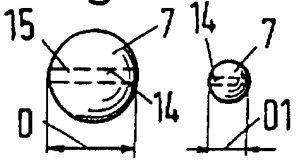


Fig. 4e

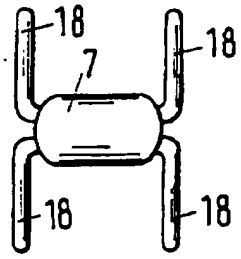


Fig. 4c

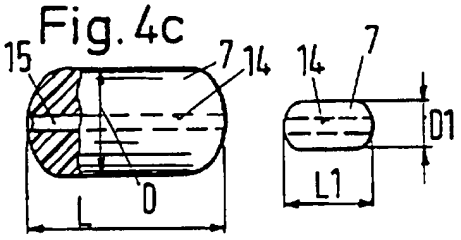


Fig. 5

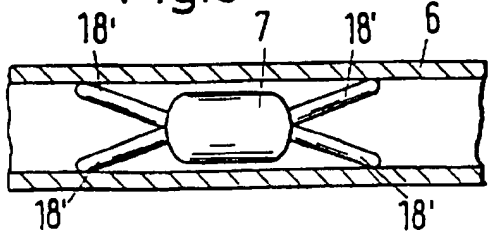


Fig. 4d

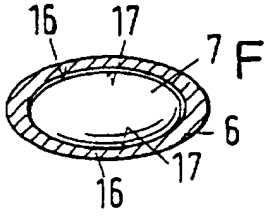


Fig. 6

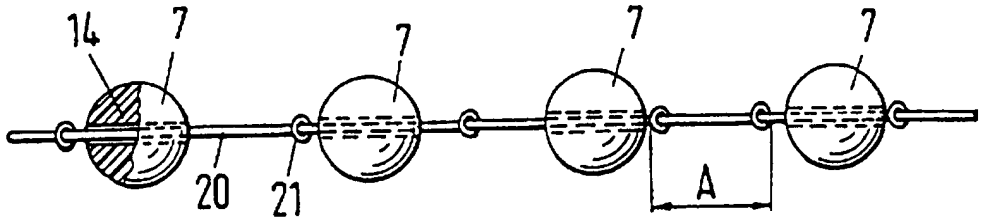


Fig. 7

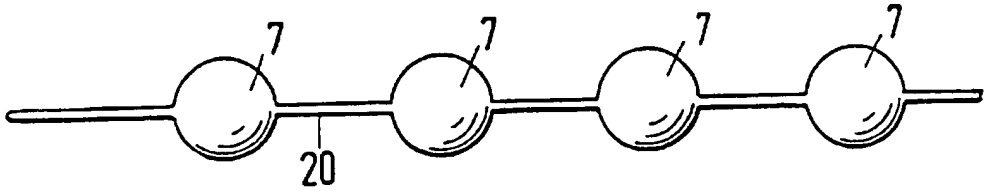
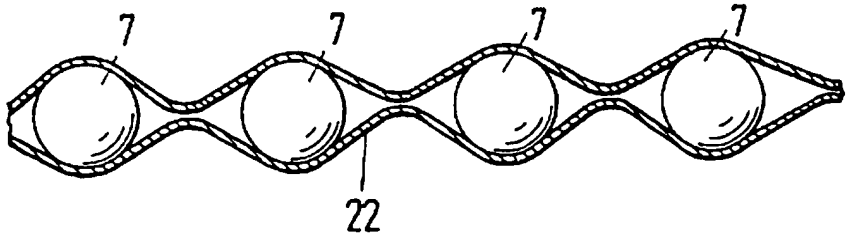


Fig. 8



INTERVERTEBRAL PROSTHESIS AND A PROCESS FOR IMPLANTING SUCH A PROSTHESIS

This is a Continuation of application Ser. No. 08/223,489 filed Apr. 5, 1994, the disclosure of which is incorporated by reference.

FIELD OF THE INVENTION

The invention relates to an intervertebral prosthesis of the type having an implant for inserting into a central cavity of the core region of an intervertebral disk and also to a process for implanting such a prosthesis.

BACKGROUND OF THE INVENTION

Known intervertebral prostheses of the above mentioned type contain implants for intervertebral disks, which via a tube can be introduced through the outer ring (anulus fibrosus) of the intervertebral disk into its core region (nucleus pulposus), in order to achieve a bearing action in the direction of the main load. Thus, EP-A-0 453 393 shows a hollow member which can be introduced into the core region of the intervertebral disk, and which can be coiled in the shape of a spiral and which can be filled in the coiled state with an incompressible fluid. Before the insertion of such an implant, the core region of the intervertebral disk, which is no longer capable of bearing loads, has to be cleared out with auxiliary tools through the hollow tube, in order to replace the non-load bearing material by the implant. As the surgeon has to work with predetermined implant sizes, he is forced to produce a matching cavity in the core region of the intervertebral disk. The known implant requires a relatively expensive design of the hollow member, in order to guarantee a permanent tightness against the egress of fluid, which is required if the implant is to work optimally.

SUMMARY OF THE INVENTION

The invention is intended to counteract these disadvantages.

The object of the invention is to create a universal, simple to apply implant, which can be used as a support member for varied cavities formed at random.

This object is achieved in accordance with the invention in that the implant contains at least three elastically deformable support members which can be inserted into the central cavity and can be positioned therein.

One advantage of the invention lies in that when creating the cavity, the surgeon only has to remove the material of the nucleus which is no longer capable of load bearing and that the quantity of support members to be inserted is necessarily established when the support members are inserted. The implant, which consists of support members which can be positioned spaced apart or touching one another and which can be made from an optional elastic material well tolerated by the body, is consequently suitable for every intervertebral disk. When the central cavity becomes clogged with the support members, they abut the boundary walls, so that a universal transfer of compressive forces and an optimal distribution in the central cavity can be achieved. During loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edge stresses in the anulus fibrosus.

Of to a preferred embodiment according to the invention, the support members can be made from an elastic plastic.

Accordingly an implant made from a suitable plastic material which can be well tolerated by the body, which can be manufactured with low expenditure and is permanently dimensionally stable, can be simply obtained.

The support members may preferably be designed in the form of rotational solids, which enable an optimal uniform transfer of the compressive forces. In this respect spherical designs are particularly advantageous.

The packing density can be increased by the use of support members having different dimensions. By providing ducts in the support members, cavities can be produced, which in contrast to solid members permit a defined, greater elastic deformation. In order to control the rigidity of the implant, a mixture of solid members and hollow members can be inserted. For the support members themselves there is a plurality of shapes, which ranges from the non-oriented spherical shape via lenticular and bean-shaped members to oblong, cylindrical, sausage-shaped members.

Several support members can be connected in chains to form a string-like, flexible support, whereby the distance between two support members advantageously corresponds at least to the diameter of one of the support members, in order to enable deviations of 180° when inserting the support members. Single-piece chains made from the same material are also possible, in which the flexible intermediate pieces are designed with a correspondingly thin shape. It is also possible to space support members with flexible tubing. The chain shape of the support members has firstly the advantage that a support member in a chain can not easily leave the central cavity through an aperture and secondly that during filling the operation can not be reversed without great time loss by withdrawing the chain. A similar retention action can be achieved on individual support members having elastically deformable expansion elements, which during insertion through the tube are deformed in the longitudinal direction and during entry into the central cavity spring back and assume a larger cross section.

A further method of depositing support members in a determined orientation lies in adapting the cross section of the tube to guide faces of the support members and depositing the support members purposefully—roughly like an insect laying its eggs—on determined sites of the central cavity, by the support member being guided in the tube and being ejected with a plunger. A lenticular member may be deposited so that, for example, its flat sides are directed against the adjacent vertebrae.

If the support members comprise a positional indicator, roughly in the form of an inclusion made from a material which is visible under X-ray examination, such as tantalum, for example, their depositing and subsequent changes in position can be controlled.

Polyurethane, for example, is suitable as the plastic for such support members. The support members may also be made from another material, e.g. a hydrogel. Corresponding support members may also be made from a suitable foam. Another design, in which each support member is formed by a cocoon-type coil consisting of a plastic thread or a metal thread, is also conceivable.

In order to increase the safety for the insertion and retention the support members, before the insertion of the support members a bag made from a synthetic woven fabric or plastic film can be introduced through the tube into the central cavity, whereby the aperture of the bag remains outside the tube. The support members are now inserted through the aperture of this bag, which aperture is supported on the tube. When the central cavity and the bag is filled with

support members, the bag can be tied off with a clamp or wire, in order to-prevent support members coming out.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features and details can be gathered from the following description of exemplified embodiments of the invention, in conjunction with the claims, represented diagrammatically in the drawings.

FIG. 1 shows a body of a vertebra in a plan view with a cross section through an intervertebral disk, which contains an implant of support members, which can be supplied via a tube;

FIG. 2 shows the intervertebral disk in a longitudinal section takes along line II—II in FIG. 1;

FIG. 3 shows a cross section through an intervertebral disk, having an implant in a modified embodiment;

FIG. 3*a* shows a cross section through a bag with support members;

FIG. 4*a*–4*e* show various embodiments of support members constructed in accordance with the invention;

FIG. 5 shows the support member shown in FIG. 4*e* in a position during insertion through a tube represented in a partial longitudinal section;

FIGS. 6, 7 and 8 show implants consisting of several support members connected to one another, in different embodiments.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIGS. 1 and 2, an intervertebral disk 3 positioned between two vertebral bodies 1 comprises an intact outer annular region 4 of natural tissue, which surrounds a central core region. In the core region is formed a cavity 5, which was previously created by the removal of the core of the damaged intervertebral disk—or a part thereof—and if necessary damaged parts of the outer annular region 4. The formation of the cavity 5 and the removal of the tissue parts which are no longer capable of load-bearing is performed in a known manner by a tubular guide part, as represented in the form of a tube 6, which, as for example in EP-A-0 453 393 mentioned at the beginning, is inserted, passing through an aperture 30 in the outer annular region 4, into the core region of the intervertebral disk 3 by a relatively slight engagement from the dorsal side between the vertebral bodies 1 and 2. A gouge is inserted into the core region through the inserted tube 6, by which the cavity 5 is created and the cut out tissue parts are removed.

An intervertebral prosthesis in the form of an implant consisting of several support members 7, which can be inserted one after the other into the cavity 5, and which are made from an elastic plastic well tolerated by the body, e.g. polyurethane, is provided as a replacement for at least one part of the core region removed. The support members 7 are constructed as rotational solids, and in the example represented in the form of balls, the dimensions of which are chosen so that they can be inserted through the tube 6 into the cavity 5. The support members 7 are packed into the cavity 5, if necessary by means of a plunger 8, until the cavity is substantially filled by the support members 7 resting against one another and the support members 5 form a new core region of the intervertebral disk 3 capable of the transfer of compressive forces. The number and dimensions of the support members 7 can be varied at random according to the dimensions given and the shape of the cavity 5 to be filled and the cross section of the tube 6. Thus for example, a design is possible which requires fewer support members 7 than the design shown, e.g. three support members 7 designed in appropriate sizes. The support members 7 can be designed with varying dimensions or, as represented, with the same diameters. A design is also possible with support members 7 disposed in a single layer, for example, which can be disposed at a distance or at varying distances from one another.

When the cavity is completely full, the tube 6 is withdrawn in a known manner from the annular region 4, whereby the through-duct—aperture 30 can be monitored, for example, by a second tubular guide part, as represented in the form of a tube 6', which can be inserted from the righthand side in FIG. 1 dorsally through an aperture 30' into the cavity 5—for the tube 6 is closed accordingly in front of the last support member 7 inserted. This may be provided, in a manner still to be described, with retention means which make it difficult for support members to leave through the through-channel.

An observation instrument 9 can be inserted through the tube 6' to monitor the clearing of the cavity 5 and/or the implantation operation or an auxiliary instrument (not represented) can be inserted to assist the clearing and implantation process. It is obvious that instead of the tubes 6, 6' represented, other suitable protective and/or guide elements of any shape and design can also be used.

In FIG. 3 the corresponding parts are provided with the same reference numbers. According to this embodiment the support members 7 can be disposed in a surrounding covering such as a bag 10, which is inserted in the empty state through the tube 6 into the cavity 5 and then filled with the support members 7 through the aperture remaining outside the tube 6. The bag 10 may be made from a woven fabric, a knitted fabric or a film made from an elastic plastic well tolerated by the body, e.g., polyethylene. When the bag 10 is filled and is connected to the support members 7 to form a compact, elastic implant suitable for transmitting compressive forces between the vertebral bodies 1 and 2, the bag 10 can be tied off by a sealing part 11, e.g. in the form of a clamp or, as shown in the drawings, a previously inserted wire loop, in order to keep the support members 7 together. After this, the end of the bag 10 is cut off and withdrawn together with the tube 6.

As can be seen in particular from FIG. 3*a*, the bag 10 can be adapted to any desired shape of the cavity 5 to be filled according to the prevailing anatomical conditions.

Numerous embodiments of support member 7 are possible. Thus, for example, instead of rotational solids, designs with polyhedral support members 7 are possible. As shown in FIG. 4*a* the spherical support members 7 in the design represented—or at least one or some of the support members 7—may be designed with a closed cavity 12, which contain an insert 13 in the form of a spherical inclusion made from a material which is visible under X-ray examination, e.g. tantalum, as a positional indicator for the respective position of the support members 7. Designs without an insert 13 are possible, in which case a correspondingly greater elastic deformation of the support member can be achieved by the cavity 12.

As shown in FIG. 4*b*, the or at least some of the support members 7 may have different diameters D or D1 and/or are designed with a duct 14 passing through them, which is open, or as represented can be provided with a rod-shaped insert 15 as a positional indicator, whereby the respective orientation of the insert 15 can be seen.

As shown in FIG. 4*c*, support members 7 can be designed with substantially cylindrical shapes rounded off at the ends.

which can also be provided with a duct **14** and/or with a rod-shaped inclusion **15**—or for example with two corresponding inclusions, offset against one another in the axial direction of the support member **7**. These support members **7** may also have different diameters D or D1 and/or different lengths L or L1.

As shown in FIG. **4***d*, the or at least some of the support members **7** can be lenticular, and in the example represented in the shape of an ellipsoid, and can be accordingly designed with defined support surfaces **16**, which permit the support members **7** to be deposited purposefully with the support faces **16** directed against the adjacent vertebral bodies **1**, **2**. As can also be seen from FIG. **4***d*, the tube **6** can be designed with a corresponding cross section, which as represented is oval, and which forms guideways **17** for the support faces **16**.

As shown in FIG. **4***e*, at least one of the support members, e.g. the last support member **7** to be inserted into the cavity **5**, can be provided with at least one, and as shown four elastically deformable expansion elements **18**, which in the expanded state protrude laterally from the support member **7** and which, as represented in FIG. **5**, are deformed when inserted through the tube **6** in the longitudinal direction into stressed positions **18'** and spring back, on leaving the tube **6**, inside the cavity **5** in the expanded state, and thus prevent the support members from leaving the cavity **5** through the through-aperture for the tube **6**.

As can be seen from FIG. **6**, several support members can be disposed in the manner of pearls on a pearl necklace on a flexible, ribbon-like or string-like support **20** and be connected thereto to form a cohesive implant. The support **20** may preferably be provided with stop parts **21** disposed between the support members **7**, as represented in the form of knots constructed on the support **20**, so that a predetermined minimum distance A is observed between the support members **7** which corresponds at least approximately to the diameter of one of the support members **7** or—in designs in which the dimensions of the support members **7** vary—the sum of the radii of the adjacent support members **7**.

As shown in FIG. **7**, the support members **7** and the support **20** are manufactured from the same material and are connected to form a single-piece implant, whereby the support **20** acts as a spacer. According to the representation shown in FIG. **8**, a number of support members **7** can be disposed in a covering in the form of tubing **22** tightly surrounding the support members **7** and can be connected thereto to form a cohesive implant. The tubing **22**, just like the bag **10**, may be formed from a corresponding woven fabric, a knitted fabric or a film.

In summary the invention can be described as follows:

An implant consisting of several support members **7**, which are produced from an elastic plastic, is provided as a replacement for a part of the core region of an intervertebral disk **3** which is no longer capable of load bearing. The support members **7** are sequentially inserted into a central cavity **5** constructed in the core region by means of a tube **6** passing though an outer annular region **4** of the intervertebral disk **3**, until said cavity is substantially filled. When the cavity **5** is clogged with the filling members **7**, they become deposited at the boundary walls of the annular region **4** and against one another and are elastically deformed under stress. Accordingly a universal implant which can be adapted to cavities **5** of any shape, and which forms a relatively compact, elastic support structure, can be achieved.

I claim:

1. An intervertebral prosthesis for an intervertebral disk having a cavity formed in a central region thereof, the prosthesis comprising an implant having at least three elastically deformable support members individually inserted into the cavity and individually positioned therein relative to each other to replace at least a part of the central region of the intervertebral disk, the support members each having a substantially fixed volume within the cavity, wherein at least one of the support members has an inner recess.

2. The prosthesis of claim **1** wherein the support members comprise an elastic plastic.

3. The prosthesis of claim **1** wherein the support members have a shape chosen from the group consisting of spherical, elliptical or cylindrical.

4. The prosthesis of claim **1** wherein the support members have varying dimensions.

5. The prosthesis of claim **1** wherein the recess comprises a duct passing through the support member.

6. The prosthesis of claim **1** wherein at least one of the support members comprises an insert made from a material that is visible under X-ray.

7. An intervertebral prosthesis for an intervertebral disk having a cavity formed in a central region thereof, the prosthesis comprising:

an implant having at least three elastically deformable support members individually inserted into the cavity and individually positioned therein relative to each other to replace at least a part of the central region of the intervertebral disk, the support members each having a substantially fixed volume within the cavity; and

an elongate, flexible support, the support members being mounted on the flexible support and spaced from each other by a minimum distance so that the support members are configured for successive and independent introduction into the cavity, the minimum distance between adjacent support members corresponding to a maximum outer dimension of at least one of the support members.

8. The prosthesis of claim **7** wherein the flexible support comprises an elongate rod passing through the support members.

9. The prosthesis of claim **7** wherein the flexible support comprises a tube surrounding each of the support members.

10. The prosthesis of claim **8** wherein the elongate rod comprises a plurality of retention members each disposed between adjacent support members for maintaining the minimum distance between adjacent support members.

11. The prosthesis of claim **8** wherein the elongate rod and the support members are made from the same material and form a single-piece implant.

12. The prosthesis of claim **7** further including a flexible outer covering surrounding the support members within the cavity, the flexible outer covering being individually inserted into the cavity and the support members being successively packed into the covering.

13. An intervertebral prosthesis for an intervertebral disk having a cavity formed in a central region thereof, the prosthesis comprising:

an implant having at least three elastically deformable support members individually inserted into the cavity and individually positioned therein relative to each other to replace at least a part of the central region of the intervertebral disk, the support members each having a substantially fixed volume within the cavity; and

a guide tube for introducing the support members into the cavity, wherein at least one of the support members comprises a guide surface that cooperates with the guide tube for positioning said one of the support members in a defined position in the cavity.

* * * * *